

K180460 Theradome LH40May 18, 2018
87 days to decisionK180460 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Feb 20, 2018
Decision date	May 18, 2018
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Theradome, Inc.
Location	Summerville, SC, US
Contact	Tamim Hamid
510(k) history	5 submissions · 5 cleared · 2012-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180460/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 30, 2026